

REMARKS

This submission is in response to the Official Action dated December 24, 2002. Claims 1-35 are pending. Consideration of the above identified application, in view of the following remarks, is respectfully requested.

Restriction Requirement

In the Office Action, the Examiner required election of one of the following groups of claims:

I. Claims 1-7 and 24-28, drawn to a transgenic non-human mammal comprising a nucleotide sequence encoding a heterologous APP₆₉₅ having specific mutations;

II. Claims 8-19, drawn to a transgenic non-human mammal comprising a nucleotide sequence encoding a heterologous APP₆₉₅ having specific mutations, and a second nucleotide sequence encoding a mutant protein;

III. Claims 20-22; drawn to a screening method for a candidate compound for preventing or delaying the development of AD;

IV. Claim 23; drawn to a screening method for a candidate compound for ameliorating the symptoms of AD;

V. Claims 29-32; drawn to a method of reducing a cognitive deficit in a mammal; and

VI. Claims 33-35; drawn to the use of an A β peptide to manufacture a medicament.

Solely to be responsive to the Examiner's restriction requirement, Group I, corresponding to claims 1-7 and 24-28, is hereby elected. This election is made with traverse, for the reasons outlined below, and Applicants reserve the right to petition therefrom under 37 C.F.R. §1.144.

Groups I and II Should Be Rejoined

It is respectfully requested that the Examiner reconsider the restriction requirement to allow prosecution of Groups I (claims 1-7 and 24-28) and II (claims 8-19) in the same application.

Under 35 U.S.C. §121, "two or more independent and distinct inventions... in one application may... be restricted to one of the inventions". Inventions are "independent" if there is no distinct relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER" (MPEP 802.01) (emphasis in original).

The Examiner argues that Groups I and II are distinct because they are drawn to transgenic animals and comprising different transgenes with different biological functions and resulting in different phenotypes. The Examiner therefore

deems Groups I and II patentably distinct, contending that they are not obvious variants. In the office action, it is also argued that separate searches would be required for Groups I and II.

Applicants respectfully disagree. The transgenic animal of Group II is a "double" transgenic animal of the "single" transgenic animal of Group I. What unifies the subject matter of Groups I and II into a single inventive concept is the specific mutations in residues 670, 671, and 717 of APP₆₉₅. By contrast, the mere concept of double transgenic animals and how to make them is well-known in the art. For example, a MedLine search for publications reciting the phrase "double transgenic" in the Abstract and published before the filing date of the present application, June 19, 2001, turned up no less than 284 references, despite the narrow scope of the search. The Examiner's contention that groups I and II are distinct since the "single" transgenic animal of group I can be used as a disease model as well as for making the "double" transgenic animal of group II is therefore moot in view of the status of the art. If the "single" transgenic animal of claim group I is patentable, so is a method for making "double" transgenic animal comprising the same, specific mutations in APP₆₉₅.

As set forth in the MPEP, section 806.05(c)II, entitled "SUBCOMBINATION ESSENTIAL TO COMBINATION":

If there is no evidence that combination AB_{sp} is patentable without the details of B_{sp}, restriction should not be required. Where the relationship between the claims is such that the separately claimed subcombination B_{sp}

constitutes the essential distinguishing feature of the combination AB_{sp} as claimed, the inventions are not distinct and a requirement for restriction must not be made, even though the sub-combination has separate utility.

Thus, whether or not the subcombination in the instant case, represented by the "single" transgenic animal, has the same or different utility than the combination, represented by the "double" transgenic animal, these two claim groups should not be restricted, and Groups I and II prosecuted in the same application.

Furthermore, regarding the prior art search, a search for literature regarding a transgenic animal expressing an APP₆₉₅ variant having K670N, M671L, and V717F substitutions (Group I) would inevitably turn up any prior art for a "double" transgenic animal expressing the same specific APP₆₉₅ variant and a second mutant protein (Group II). The Examiner has also classified the subject matter of Groups I and II into the same class (800) and subclass (8+).

Finally, all claims of Group II depends directly or indirectly from claims in Group I and include the same recitations of the specific APP₆₉₅ mutations in residues 670, 671, and 717. Therefore, the subject matter of Group II cannot be examined without examination of the subject matter of Group I.

Accordingly, for all of the above reasons, the claims of Groups I and II, *i.e.*, claims 1-19 and 24-28, should be examined in the same application.

Reconsideration of the restriction requirement as applied to Groups I and II is thus respectfully requested.

Election Requirement

The Examiner also issued species election requirements if claim group II were to be elected. In order to advance prosecution in case the Examiner decides to rejoin claim group II with elected claim group I, Applicants hereby constructively elect (1) presenilin as the selected protein, and (2) presenilin 1 L286V and M146L double mutation as mutant. Claims 8, 9, 12, 15, and 16 read upon the elected protein species, and claims 12 and 19 read upon the elected mutant species.

It is noted that, upon allowance of a generic claim, Applicant is entitled to consideration of claims to additional, non-elected species.

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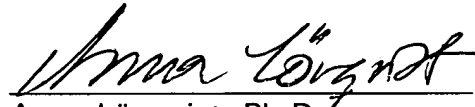
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Early and favorable consideration of this response and the claims is earnestly solicited.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's

Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Anna Löqvist", is written over a horizontal line.

Anna Löqvist, Ph.D.

Limited Recognition Under 37 C.F.R.

10.9(b) (see attached)

Representative of Applicants

DARBY & DARBY, P.C.
Post Office Box 5257
New York, NY 10150-5257
Phone (212) 527-7700



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Expires: February 4, 2004

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Director of Enrollment and Discipline

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